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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,983	06/15/2000	William C. Olson	57906-B/JPW/SHS	8686

7590 12/03/2002

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EXAMINER	
FOLEY, SHANON A	
ART UNIT	PAPER NUMBER
1648	15

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/594,983	Applicant(s) OLSON ET AL.	
	Examin r Shanon Foley	Art Unit 1648	

-- Th MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *98-116* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *99* is/are allowed.

6)☒ Claim(s) *98,100-104 and 106-116* is/are rejected.

7)☒ Claim(s) *105* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

In paper no. 12, applicant cancelled claims 78-97, amended claims 98, 99, and added new claims 100-116. Claims 98-116 are under consideration.

Claim Objections

Claim 105 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, claim 105 has not been further treated on the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 98, 100-104 and 106-116 are provisionally rejected under the judicially created doctrine of double patenting over claims 78-80 of copending Application No. 09/464,902 for reasons of record. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Applicant traverses the rejection on the grounds that the antibodies are not being examined in the '902 application due to an election of a group drawn to nucleic acids.

Applicant's arguments have been fully considered, but are found unpersuasive because there is no record of an election in the '902 application. Further, even if the election were of record, claims to the monoclonal antibodies are still pending in both applications. To obviate this rejection, it is suggested that applicant cancel the monoclonal antibody claims in the '902 application, i.e. claims 78-80.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 106 and 109-115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 106 is drawn to a monoclonal antibody or a fragment thereof that specifically binds to an epitope on CCR5. The claim states that the epitope comprises two amino acid sequences. One is a "portion" of the amino terminal region and the second sequence comprises a "portion" of an extracellular loop region 2 (ECL2). The metes and bonds of the "portions" recited in the claims are vague and indefinite. Also, section (b) of the claim recites "at a defined concentration", but does not recite what the concentration is and it cannot be determined what the "same defined concentration" is in section (c). This rejection affects claims 109-115.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 106, 109, 111, 112, and 114-116 are rejected under 35 U.S.C. 102(a) as being anticipated by Wu et al. (WO 98/18826).

Claim 116 is drawn to a monoclonal antibody comprising a single set of light and heavy chain CDRs that bind to an epitope located in the N-terminus and one of the three extracellular loops of CCR5. Claim 106 is drawn to a monoclonal antibody or a fragment that specifically binds to an epitope on CCR5 that comprises at least two amino acid sequences. The first sequence comprises a potion of the N-terminal region of CCR5 and the second sequence comprises a portion of the ECL2. This antibody inhibits HIV-1 infection of a CD4+ CCR5+ cell and does not antagonize the activity of CCR5 in response to certain chemokines listed in claim 109.

Wu et al. teaches a bispecific antibody that binds to the N-terminus and the second extracellular loop of CCR5, see page 15, line 27 to page 16, line 5. This antibody clearly anticipates claim 116 and 106. Wu et al. teaches that this antibody inhibits HIV infection of a cell, see claim 12, and inhibits the interaction between CCR5 and one or more of its ligands, such as RANTES, MIP-1α and MIP-1β, see page 19, lines 11-14 and claims 5, 30 and 31.

Claims 111 and 112 are drawn to the antibody comprising a human immunoglobulin molecule. Wu et al. teaches humanized forms of the antibodies, where the framework and the consensus are derived from a human immunoglobulin or multiple immunoglobulin molecules, see page 19, line 31 to page 21, line 32.

Claims 114 and 115 are drawn to the antibody labeled with a detectable marker. Wu et al. teaches a method of detecting the expression of CCR5 on a cell by detecting the binding of

the antibody to the cell, see claim 16 for example. Although Wu et al. does not explicitly teach that the antibody is labeled, the antibody of claim 16 would have to possess a label for its presence to be detected. Wu et al. also teaches identifying an agent with a fluorescent or radioactively labeled antibody, see claims 62 and 64.

Applicant argues that the bispecific antibody of Wu et al. recognizes at least two different epitopes and that the antibody of Wu et al. does not anticipate the instant invention. Applicant asserts that the claimed antibody is monospecific and recognizes one non-contiguous epitope on CCR5.

Applicant's arguments have been fully considered, but are found unpersuasive. The claims are drawn to a monoclonal antibody that binds to an epitope comprising the N-terminus and ECL2. Therefore, the instant antibody is bi-specific for two different amino acid sequences in different regions of the CCR5 molecule. The antibody of Wu et al. is also bi-specific for the N-terminus and ECL2 and recognizes the identical epitope recited in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 113 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. *supra*.

The claim is drawn to specific human immunoglobulin molecules, such as IgG1.

See the teachings of Wu et al. above. The reference does not teach specific immunoglobulins listed in the claims. However, Wu et al. teaches antibodies in humanized form

where the framework is derived from a human immunoglobulin. Therefore, any specific human immunoglobulin would be an obvious choice to the ordinary artisan.

Allowable Subject Matter

Applicant has rewritten claim 99 in independent form and is allowable.

Claim 110 is not anticipated by the Wu et al. because the epitope of PA14 is D2 in the N-terminus and R168 of in ECL2, see the specification on page 38, lines 11-13. Although Wu et al. anticipates an antibody that binds to the N-terminus and ECL2 of CCR5, the reference does not teach that the antibody binds to these specific amino acid sequences.

On page 17 of the response, applicant states that page 10 of the Office action indicated that antibodies having specificity to a conformational epitope that comprises the N-terminus and the second extracellular loop of CCR5 is not taught or suggested by the prior art. However, this statement is incorrect, as evidenced by the teachings of Wu et al. cited on page 6 of the previous rejection and the instant rejection under 35 U.S.C. § 102. The indicated allowable subject matter is drawn to the specific antibodies recited in originally presented claim 98.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
November 20, 2002

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600